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San Diego, CA 92129
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5739 '03 AUG 29 P2:10
August 18, 2003

Office of Nutrition Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
Harvey W. Wiley Building
HFS-810
College Park, MD 20740

AUG 17 2003

Re: Section 403(r)(6) Dietary Supplement Notification

To Whom It May Concern:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) we are notifying the Food and Drug Administration (FDA) that we have introduced into interstate commerce a dietary supplement that contains a structure/function claim. We are providing the following information as required by 21 CFR 101.93(a)(2):

1. Name and Address of the Manufacturer:

Lignan Research, 4936 Lake Terrell Road, Ferndale, WA 98248

2. Text of the Statements:

Brevail® is the first natural product to proactively address the maintenance of orderly cellular division in the preservation of healthy breast tissue.

Research suggests that our bodies use natural plant lignans, now sparse in the diet, to buffer and balance potentially adverse effects of estrogens.

Brevail® was researched and developed to increase lignan concentrations in the body to match levels found in women who collectively demonstrate an extraordinary history of breast health.

3. Name of the Dietary Ingredient

Lignans (derived from flaxseed).

85672

975 0162

LET

12748

4. Name of the Dietary Supplement

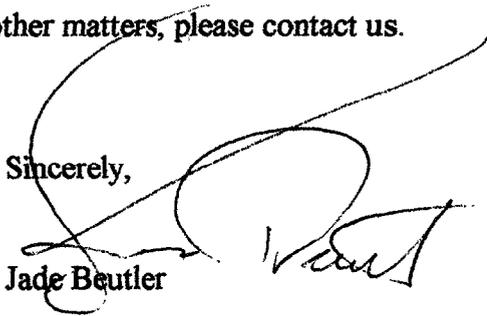
Brevail®

I certify that the information contained in the notice is complete and accurate, and that Lignan Research has substantiation that the statements are truthful and not misleading.

If you have any questions on this or other matters, please contact us.

Sincerely,

Jade Beutler

A handwritten signature in black ink, appearing to read 'Jade Beutler', is written over the printed name. The signature is fluid and cursive, with a large loop at the top.